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EXAMINER

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1634

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/507,167 | <b>Applicant(s)</b><br>PASZKOWSKI ET AL. |  |
|                              | <b>Examiner</b><br>BJ Forman         | <b>Art Unit</b><br>1634                  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12, 13 and 15-28 is/are pending in the application.
- 4a) Of the above claim(s) 4-9 and 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 12, 13 and 25-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 21 April 2008 in which claims 1, 9, 12 and 25 were amended and claims 10-11 and 14 were canceled. The amendments have been thoroughly reviewed and entered.

The previous objects and rejections in the Office Action dated 19 November 2007 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 1-3, 12-13, 25-28 are under prosecution.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 12-13, 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Fulwyler et al (U.S. Patent No. 6,610,499, filed 31 August 2000).

Regarding Claim 1, Fulwyler et al teach a microcapillary hybridization chamber comprising a narrow bore tubing (Column 8, lines 1-18). Fulwyler et al teach the capillary has a plurality of oligonucleotide probe segments (Column 11, line 58-Column 12, line 24), the probes are covalently attached to the inner wall of the tubing (Column 16, lines 19-42) wherein each segment has the same probe and different segments have different probes (Column 17, lines 53-63) and wherein the probe have known sequences (e.g. Column 32, lines 35-37). Fulwyler et al further teach the microcapillary wherein an electrode underlies each of the probe segments (Columns 20-21, especially, Column 21, lines 42-45) whereby an electrical potential is applied separately to each probe segment allowing different stringency of hybridization (Column 26, lines 4-22).

It is noted that the claim defines an intended use for the hybridization chamber i.e. electrical potential is applied...allows for different levels of stringency.

Fulwyler et al teach electronic stringency as recited. However, Applicant is reminded that the courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Regarding Claim 12, Fulwyler et al teach the device wherein each segment comprises e.g. DNA, RNA, synthetic oligonucleotides (Column 12, lines 14-59).

Regarding Claim 13, Fulwyler et al teach the device wherein the probe segments are distinguishable from each other (Column 17, lines 64-67).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulwyler et al (U.S. Patent No. 6,610,499, filed 31 August 2000) in view of Suyama (U.S. Patent No. 6,559,296, filed 21 February 2001).

Regarding Claims 2-3, Fulwyler et al teach a microcapillary hybridization chamber comprising a narrow bore tubing (Column 8, lines 1-18). Fulwyler et al teach the capillary has a plurality of oligonucleotide probe segments (Column 11, line 58-Column 12, line 24), the probes are covalently attached to the inner wall of the tubing (Column 16, lines 19-42) wherein each segment has the same probe and different segments have different probes (Column 17, lines 53-63) and wherein the probe have known sequences (e.g. Column 32, lines 35-37).

Fulwyler et al clearly suggests that the device of Claim 1 has at least 1,000 segments/cm (Column 17, line 58-Column 18, line 5).

However, capillaries having closely spaced probe segments separated by 1 $\mu$ m were well known in the art at the time the claimed invention was made as taught by Suyama (Column 8, lines 10-15).

Suyama teaches a hybridization chamber similar to that of Fulwyler et al wherein the capillary has probe segments, each segment having the same oligonucleotide probe covalently attached to the inner wall and separated by 1 $\mu$ m (Column 8, lines 5-15 and Column 9, line 36-Column 10, line 35).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the probe segment spacing of Suyama to the capillary of Fulwyler et al to provide segment densities of 500 or 1,000 segments per cm. One of ordinary skill in the art would have been motivated to do so based on the closely spaced probe segments suggested by Fulwyler (Column 17, line 58-Column 18, line 5). Hence, it would have been obvious to applied the immobilization techniques taught by Suyama to the capillaries of Fulwyler so as to provide closely spaced probes (e.g. 1000 per cm) as was well known in the art.

6. Claims 25-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Fulwyler et al (U.S. Patent No. 6,610,499, filed 31 August 2000) in view of Shalon et al (U.S. Patent Application Publication No. 2001/0051344, published 13 December 2001).

Regarding Claim 25, Fulwyler et al teach a microcapillary hybridization chamber comprising a narrow bore tubing (Column 8, lines 1-18). Fulwyler et al teach the

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capillary has a plurality of oligonucleotide probe segments (Column 11, line 58-Column 12, line 24), the probes are covalently attached to the inner wall of the tubing (Column 16, lines 19-42) wherein each segment has the same probe and different segments have different probes (Column 17, lines 53-63) and wherein the probe have known sequences (e.g. Column 32, lines 35-37). Fulwyler et al further teach the microcapillary wherein an electrode underlies each of the probe segments (Columns 20-21, especially, Column 21, lines 42-45) whereby an electrical potential is applied separately to each probe segment allowing different stringency of hybridization (Column 26, lines 4-22).

Fulwyler et al further teach the device comprising a detector, computer and program for controlling the detector (Column 22, lines 37-45, Column 31, lines 30-38). Fulwyler et al is silent regarding display of the detected signals

Regarding Claim 26, Fulwyler et al teach the detector comprises excitation optics for focusing light on probe segments (Fig. 7, Column 31, lines 30-38).

Regarding Claim 27-28, Fulwyler et al teach the computer system collects and processes data from the processor (Column 22, lines 37-45, Column 31, lines 30-38) but do not teach fluorescence intensity determination, removing data outliers, calculating binding affinity or probe color display.

However, programmed detection of hybridization signals were well know and routinely practiced as suggested by Fulwyler and as taught by Shalon et al (¶ 202).

Shalon teaches the processor determines the intensity of fluorescence, removal of outliers based on normalization calibrations, determines relative binding affinity and

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displays color signals (§§ 149-150, 196-204) whereby the signals are analyzed digitally to quantitatively measure hybridization reactions (§§ 202-204). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the programmed analysis of Shalon to the computer processing of Fulwyler. One of ordinary skill in the art would have been motivated to do so based for the expected benefit of obtaining quantitative measurement of hybridization reactions as taught by Shalon (§§ 202-204).

### ***Conclusion***

7. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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